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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/532,787	05/23/2006	Jonathan Michael Blackburn	27353-514-US1	3797

35437 7590 10/07/2009
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EXAMINER

GITOMER, RALPH J

ART UNIT	PAPER NUMBER
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1657

MAIL DATE	DELIVERY MODE
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10/07/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/532,787	Applicant(s) BLACKBURN ET AL.	
	Examiner Ralph Gitomer	Art Unit 1657	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 August 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 37-54 and 56-65 is/are pending in the application.
- 4a) Of the above claim(s) 60 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 37-54, 56-59, 65 and 611 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>5/11/09</u> . | 6) <input type="checkbox"/> Other: _____ |

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The RCE request received 8/3/09 and the amendments received 8/7/09 and IDS received 5/11/09 have been entered. Claims 37-54, 56-59, 61-65 are considered here. Please update the continuing information in the preamble of the specification.

Although not claimed, it appears the point of novelty of the invention as described in the specification resides in the polyethylene glycol coating to repel protein on the probe surface. See paragraph 58 in the present specification. Further, some of the dependent claims are directed to a specific buffer as discussed in paragraph 28 of the present specification. All the rest of the claimed features are well known in Maldi technology and are not considered here further.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 37, 3954, 57, 59, 62, 63-65 are rejected under 35 U.S.C. 102(b) as being anticipated by Nelson.

Nelson (Mass Spec Rev) entitled “The Use of Bioreactive Proves in Protein Characterization” teaches in the abstract standard Maldi analysis. On page 356 Fig. 1 describes a standard Maldi probe where enzymes may be attached to the activated surface which is coated in gold. On page 357 column 1 last paragraph bridging to column 2, standard Maldi digests are discussed. On page 371 column 1 last paragraph

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bridging to column 2 enzyme specificity determinations are described where inhibitors are screened.

All the features of the claims are taught by Nelson for the same function as claimed.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 37-54, 56-59, 61-65 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of Wagner in view of Kolster.

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Wagner (WO 00/04382) entitled "Arrays of Proteins and Methods of Use Thereof" teaches on page 12, on the probe there is an organic thin film of polyethylene glycol which reduces the non-specific binding of molecules to the surface. Exposed functionalities serve to tether the thin film to the surface of the substrate or the coating. Other functions of the coating are discussed. On page 32 last paragraph affinity tags with a given functionality on the organic thin film are discussed.

The invention differs from Wagner in that the buffer selected is ammonium carbonate.

Kolster (6,258,538) entitled "DNA Diagnostics Based on Mass Spectrometry" teaches conventional Maldi in a number of standard applications. In column 19 line 52 ammonium carbonate buffer is shown on a mass spec platform.

It would have been obvious to one of ordinary skill in this art at the time of the invention to perform standard Maldi analysis as shown by each of the above references with a volatile buffer such as ammonium carbonate as shown by Kolster because no buffer residue would be left on the probe when dried. Employing a known buffer for its known function with the expected results would have been obvious.

Applicant's arguments filed 8/3/09 have been fully considered but they are not persuasive.

Applicants response argues that the invention is directed to a label free detection system to interrogate enzymatic reactions. Wagner is directed to antibody binding and not to enzyme mediated catalysis. Kolster does not teach determining activity of an enzyme with mass spec.

It is the examiner's position that Wagner teaches on page 12 the function of the thin film is to enable certain detection techniques to be used with the surface and prevent inactivation of protein immobilized on the surface. On page 17 last paragraph the proteins immobilized on the surface include enzymes, examples are kinases, phosphatases, hydrolases. On page 46 non-label detection methods are generally preferred. On page 48 enzyme substrate interactions are studied and the interaction may involve catalysis. Kolster teaches conventional MALDI which includes the steps of (i) – (vi) as seen in present claim 37 which are all conventional MALDI steps but not the protein repellent compound layer. The present claims are not directed to a label free detection system.

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Claims 37-54, 56-59, 61-65 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for polyethylene glycol bound with a poly amino acid, does not reasonably provide enablement for a layer resistant to non-specific protein binding comprising protein repellent molecules. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

In claim 37 the terms "a layer resistant to non-specific protein binding comprising protein repellent molecules" lack enablement as it would require one of ordinary skill in this art undue experimentation to determine which such layer would work in the instant invention.

On page 12 of the present specification first paragraph, the protein repellent molecules are described in connection with binding moieties as related to the enzyme being tested. This is an essential feature of the claimed invention.

The number of required characteristics of the claimed layer is considerable beyond repelling proteins and one of skill in this art would not know what compounds would meet such characteristics.

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The entire scope of the claims has not been enabled because:

1. Quantity of experimentation necessary would be undue because of the large proportion of inoperative compounds claimed.
2. Amount of direction or guidance presented is insufficient to predict which substances encompassed by the claims would work.
3. Presence of working examples are only for specific substances and extension to other compounds has not been specifically taught or suggested.
4. The nature of the invention is complex and unpredictable.
5. State of the prior art indicates that most related substances are not effective for the claimed functions.
6. Level of predictability of the art is very unpredictable.
7. Breadth of the claims encompasses an innumerable number of compounds.
8. The level of one of ordinary skill in this art is variable.

In re Wands, 858 F.2d 731, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988).

Applicant's arguments filed 8/3/09 have been fully considered but they are not persuasive.

Applicants response argues that the coating is described in paragraph 60 of the specification.

It is the examiner's position that the description provided in the specification for the coating, which is the singular point of novelty of the claimed invention, is only broadly described and insufficient for one of skill in this art to make and use the invention. For example, polyethylene glycol with a functional group that may be attached via a linker encompasses a plethora of different compounds, most of which will not work in the claimed invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 37-54, 56-59, 61-65 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Each of the following applies in all occurrences.

There are a number of instances of lack of antecedent basis in the claims, see claim 37 line 1, "the activity", last line, "the probe surface". In claim 37(ii) no function is seen in the claim for the test compound which is confusing. In claim 37 "protein repellent molecules" does not sufficiently define what substances are desired in the layer to know the metes and bounds of the claim. For example, the terms may include water or air or glass. In claim 38 "self-assembled monolayers molecules" is not understood in context and reads on water vapor. In claim 39 and all occurrences "such as" is improper. In claim 40 "one or more kinases" lacks antecedent basis. In claim 61 "an-ammonium" may be a typo. In claim 65 line 4 "or non-protein kinase or an

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oxidoreductase" is not understood and is in improper Markush format. Further, the group is of enzymes and a G-protein coupled receptor, an ATP dependent chaperone are not enzymes.

The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ralph Gitomer whose telephone number is (571) 272-0916. The examiner can normally be reached on Monday - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber can be reached on (571) 272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Ralph Gitomer/
Primary Examiner, Art Unit 1657

Ralph Gitomer
Primary Examiner
Art Unit 1657